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EXAMINER	
ROBINSON, D	
ART UNIT	PAPER NUMBER
125	3

DATE MAILED: 08/03/88

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 2/5/88 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449
4. ☐ Notice of informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-12 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1-12 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.

8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable; ☐ not acceptable (see explanation).

10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved. ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.

12. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

Claims 1-12 are presented for examination.

The amendment filed February 5, 1988 have been received and entered.

Claims 1-12 are rejected under 35 USC 112, first paragraph, as the disclosure is enabling only for claims limited in accordance with pages 2-9 of the specification. See MPEP 706.03(n) and 706.03(z).

Specifically the following terminology is deemed to encompass a scope of subject mater which is broader than warranted or supported by the limiting enabling disclosure presented herein: "a basic active" (claims 1, 3, 7); "an anionic -- polymer" (claims 1, 3, 7); "a cation resin" (claims 1, 3, 7); "the basic active is -- isoxaprolol" (claims 6 and 12).

While functional language is permitted it must serve to define that to which it is directed. The claims remain drawn to an undetermineable number of undefine compositions. Thus the claims fails to meet the requirements of 35 USC 112, first paragraph.

Claims 1-12 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 are indefinite in failing to set forth proportions for all ingredients present therein. Similarly, claims 7-12 are indefinite in failing to set out the amount of active ingredient or composition containing same to be administered in the claimed method. Claims 1, 3 and 7 are indefinite in that the term "controlling" is indefinite as to just what type of effect is desired or expected. Claims 1, 3 and 7 are rendered indefinite by the expressions "a basic active", "an anionic--polymer" and "a cation resin" which fail to clearly identify all ingredients present which are critical to pointing out and distinctly claiming the invention.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at

the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

claims 1-12 are rejected under 35 USC 103 as being unpatentable over Micheals (A), Schoenwald et al. (F) Schoenwald et al (G) in view of Rankin (C) Mamajek et al (E), Samejima et al (H) and Health et al (R).

Michaels, Schoenwald et al and Schoenwald et al disclose ophthalmic compositions wherein the active ingredients, including those names herein, are administered to the eye in combination with a polymeric carrier. The Carbopol type polymers are specifically named. The use in this type of composition of a cation exchange resin would be obvious in view of Rankin, Mamajek et al., Samejima et al and Health et al. These references disclose these cation exchange resin as carriers for ophthalmic medicaments. Note that "Amberlite" is specifically named. Further, Rankin

teaches the compatability of these resins with many of the other polymeric carrier systems which are conventionally used for ophthalmic application. The use of the combination of the two for a carrier system is deemed well within the purview of the skilled artisan given the characteristics of each as disclosed by the references. Slight variations of proportions are deemed determinable by those skilled in the art.

The rejection is further based on the well established principle of patent law that no invention resides in a combination of old ingredients of known character where the results obtained is no more than the additive effect of the characteristics of the components. In the instant claimed invention, the active ingredients are known and the carrier components are old for use in this very type of composition. In the absence of evidence of unexpected results, the claimed invention is prima facie obvious over the cited art and unpatentable as such.

Applicants appear to allege criticality as to the presents of lecithin. Yet these ingredients are not demonstrated to yield any results when added to the other ingredients. Particularly since the amounts of each are not specified, the importance of these ingre-

dients is not reflected in the instant claims. Further, the use of all three ingredients is taught to be conventional for this very type of application. That applicants may have a different purpose for addition of a specific ingredients does not indicate patentability in the absence of evidence of unexpected results.

Applicants also argue that the references themselves must suggest the combination. However in fact the references do just that; all deal with ophthalmic medicaments and the various components to be used therein. Further each component is shown to be beneficial when added to such a composition. This is surely motivation to add these ingredients to just this type of composition.

Applicants allege improved method in the claimed invention. No comparative study has been submitted to support this allegation. Sustained release medicaments for the eye are old. All components of the claims are shown to old and of known character. Absence a clear and convincing showing of results other than what one skilled in this art would expect, the claims fails to patentably distinguish over the cited art. Further, it should be noted that any such showing must be commensurate in scope with the claimed subject matter. For

these reasons, the rejection is deemed proper and is adhered to.

B, D and I are cited to further show the state of the art.

The current status of all parent applications should be set forth on page 1 of the specification.

No claims are allowed.

DWROBINSON:wdh
A/C 703 557-3920
8/2/88

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PRIMARY EXAMINER
ART UNIT 125